K050443

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510K SUMMARY

SEP 0 2 2005

Submitter's Name:	KENTEC MEDICAL, INC.
Address:	17871 FITCH, IRVINE, CA 92614, USA
Telephone No.:	949 863-0810
Contact Person:	DAVID SHERATON
Date:	APRIL 25, 2005
Common or Usual Name:	NEONATAL PEDIATRIC ECG ELECTRODE
Classification Name:	ELECTRODE, ELECTROCARDIOGRAPH
Proprietary Name:	Accu-Lead

INFORMATION ON DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

510(k) Number	Proprietary Name	Manufacturer
K011564	Neolead	Neotech Products

COMMON TECHNOLOGICAL CHARACTERISTICS

1. Silver Silverchloride Sensing Eyelet
2. DIN Standard Socket Safety Lead Wire
3. Hydrogel
4. Nonwoven Backing

PERFORMANCE DATA COMPARISON NONCLINICAL TEST

510(k) Number	Proprietary Name	Manufacturer	NON-CLINICAL TEST
K011564	Neolead	Neotech Products	ANSI/AAMI EC12-1991
K011564	Neolead	Neotech Products	ANSI/AAMI EC53:1995/(R)2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 2 2005

Kentec Medical, Inc.
c/o Mr. David Sheraton Sr.
President & CEO
R & D Medical, Inc.
20492 Crescent Bay Drive, Building 106
Lake Forest, CA 92630

Re: K050443
Trade Name: Neonatal Pediatric ECG Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: August 9, 2005
Received: August 9, 2005

Dear Mr. Sheraton:

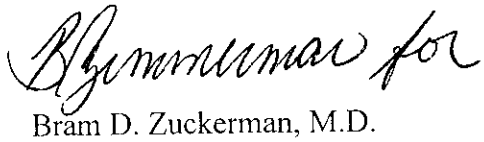
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

M203/510K/0415A05

Indications for Use

510(k) Number (if known): K050443

Device Name: NEONATAL PEDIATRIC ECG ELECTRODE

Indications For Use:

Single Use Only - Disposable

The NEONATAL PEDIATRIC ECG ELECRODE is intended for use whenever cardiac monitoring of neonatal or pediatric patients is deemed or desirable by trained medical or emergency personnel. This electrode is for use on the surface of the body.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050443